IABS 12th Annual Statistics Workshop: From Data to Patients – CMC Statisticians Contributions to Quality, Safety, and Efficacy of Pharmaceutical Products

October 20-22, 2026 – Rockville, U.S.A.

Every analysis, model, and decision in Chemistry, Manufacturing, and Controls (CMC) ultimately serves one goal—improving patient outcomes. CMC statisticians are at the forefront of this mission, ensuring that pharmaceutical products meet the highest standards of quality, safety, and efficacy.

Like chefs transforming ingredients into a finished dish, statisticians transform data using their knowledge, methodologies, and software, into insights that support sound decision making. In a regulated environment, our work is rigorously evaluated by health authorities, much like critics assessing whether a Michelin star is deserved. As Dr. Ji Hyun Lee, former ASA President, remarked: "I truly value every data point in my hand, because each one represents a patient's story, struggle and journey." This mindset reflects the broader reality across CMC: behind every data point is a patient, and our analytical rigor directly contributes to ensuring their safety and well-being.

This conference will highlight the critical role of statisticians across the CMC lifecycle through four core sessions:

1. **Data** –The early role statisticians can play in shaping data systems, improving data quality, as well as managing and leveraging increasingly complex datasets.

2. **Software** – The importance of reliable software—both point and click and code based—, and their appropriate use, in producing sound statistical analyses in a regulated environment.

3. **Methodologies** – Three mini-keynotes highlighting the evolving landscape of statistical methodologies within CMC:
    - The fundamental role of **frequentist statistics** in CMC decision-making
    - The growing influence of **Bayesian methods** in uncertainty quantification, inference, and modeling
    - The potential of **AI and machine learning** for predictive modeling and process optimization

4. **Regulatory Review** – Perspectives from global health authorities on key statistical considerations in regulatory submissions.

Additionally, a **workshop** will provide practical overviews of the role SAS, JMP and R have in helping us transform data into insights.

This program reflects the Big Tent vision of statisticians' contributions to healthcare and reinforces the vital connection between statistical rigor and patient well-being.

Scientific / Organizing Committee

Ruojia **Li** – BMS (Co-Chair)
Jia **Liu** – Pfizer (Co-Chair)
José **Ramírez** - Kite Pharma, a Gilead Company (Co-Chair)
George **Atkins** – Genentech
Timo **Bailer** - Boehringer Ingelheim
Madinina **Cox**, Events Manager, IABS/MC'Com
Fang **Chen** – SAS
Catherine **Cheng** – Novartis
Jennifer **Kirk** – FDA
Irina **Gershgorin** – Legend Biotech
Ruojia **Li** – BMS (Co-Chair)
Ashley **Giambrone** – Regeneron
Brooke **Marshall** - Eli Lilly & Co.
Oluyemi **Oyeniran** – Johnson & Johnson
Laura **Pack** – Moderna
Christopher **Thompson** – AstraZeneca
Travis **Wolter** – Amgen
Jie **Zhao** – Merck

Workshop Program

Day 1: Tuesday, October 20, 2026

8.30am	*Registration & Welcome Coffee*
9.00 am	*Introduction to IABS* *Welcome to Workshop* **Ruojia LI** – Co-Chair, BMS **Jia Liu** – Co-Chair, Pfizer José **Ramírez** - Co-Chair, Kite Pharma, a Gilead Company

Keynote Session

9.15 am	More Than Numbers: How Everyday Statisticians Shape Science Prof. Ji-Hyun **Lee** – University of Florida

Session I: Data

Session Chairs: Brooke Marshall & Ashley Giambrone

10.15 am	*Session introduction* Brooke Marshall & Ashley Giambrone
10.20 am	From Data Foundations to Data Products: The Statistician's Role in Shaping CMC Data Strategy and Driving Scalable Analytics Dan **Liu**, Ruojia **Li** – BMS
10.50 am	Beyond the Spreadsheet: Strengthening CMC Data Governance as the Foundation for Advanced Analytics and Regulatory Compliance Sara **Cook**- IliaCook Statistical Consulting, LLC.
11.20-11.35 am	Break

11.35 am	From Data to Insight: Enabling Scalable, GxP-Compliant Analytics Through an Integrated Data Lake Brenda **Ramirez** – Kite Pharma, a Gilead Company ***(remotely)***
12.05 am	Panel Discussion All speakers
1.05-2.05 pm	*Lunch Break*

Session II: Software

Session Chairs: Travis Wolter & Fang Chen

2.05 pm	*Session Introduction* Travis Wolter & Fang Chen
2.10 pm	Transforming Clinical Research with Generative AI in SAS Viya Pankaj **Attri -** SAS
2.40 pm	Beyond Control Charts: Adaptive, Model-Based Condition Monitoring with Generative AI for Biomanufacturing Process Monitoring Mark **Wolff** - SAS
3.10 pm	BPC-Stat: An Integrated Software Ecosystem for Automated Process Characterization and Statistical Modeling Melissa **Matzke** & Seth **Clark**, Merck & Co.
3.40-3.55 pm	Break
3.55 pm	Panel Discussion All speakers
4.55 pm	*End of Day 1*

Day 2: Wednesday, October 21, 2026

8.30am	*Registration & Welcome Coffee*

Session III: Methodologies

Session Chairs: Laura Pack, Timo Bailer

9.00 am	*Session introduction* Laura Pack & Timo Bailer
9.05 am	Mini Keynote – The fundamental role of frequentist statistics in CMC decision making Rick **Burdick**, Burdick Statistical Consulting, LLC

9.35 am	Mini Keynote – The growing influence of Bayesian methods in uncertainty quantification, inference, and modeling in CMC studies Stan **Altan**, Johnson&Johnson ***(remotely)***
10.05 am	Let Models Speak: Machine Learning Process Models with Interpretable AI Agents Gang **Wang**, Moderna
10.35-11.00 am	Break
11.00 am	Panel Discussion All speakers
12.00-1.00 pm	*Lunch Break*

Session IV: Regulatory Review

Session Chairs: Catherine Njue, Health Canada & Jennifer Kirk, FDA

1.00 pm	*Session Introduction* Catherine Njue & Jennifer Kirk
1.05 pm	Application of Bayesian Methodologies in CMC Statistics – Areas of Focus Mark **Quinn,** Health Products Regulatory Authority (HPRA)
1.35 pm	Parallelism Testing Methods for Potency Bioassay Curves Dr. Meiyu **Shen**, CDER/FDA
2.05 pm	Considerations for Bayesian-Informed CMC Regulatory Submissions Jun **Gao,** BRDD / Health Canada ***(remotely)***
2.35-2.50 pm	Break
2.50 pm	Panel Discussion All speakers
3.50 pm	Discussion on Predictive Modelling Moderators: Travis Wolter, Ruojia Li & Jia Liu
4.50 pm	*End of Day 2*

Day 3: Thursday, October 22, 2026

8.30 am	*Registration & Welcome Coffee*
9.00 am	Workshop 1 by JMP: Automating CMC Analytic Workflows with JMP Jeff **Upton** – JMP
10.00 am	Workshop 2 by R: AI Tooling for Data Analysis Max **Kuhn** - Posit PBC

11.00 am – 11.25 am	Break
11.25 am	Workshop 3 by SAS Fang **Chen** – SAS
12.25 pm	*Workshop Summary*
12.40 pm	*End of Workshop and Invitation to 2027 Workshop*